**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF ILLINOIS**
**EAST ST. LOUIS DIVISION**

**UNITED STATES OF AMERICA; THE COMMONWEALTHS OF MASSACUSETTS AND VIRGINIA, THE STATES OF CALIFORNIA, DELAWARE, CONNECTICUT, MARYLAND, COLORADO, FLORIDA, GEORGIA, ILLINOIS, INDIANA, HAWAII, MICHIGAN, MONTANA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, NEVADA, TENNESSEE, TEXAS, NEW JERSEY, RHODE ISLAND, OKLAHOMA, WISCONSIN, NORTH CAROLINA, AND MINNESOTA, THE CITY OF CHICAGO AND THE DISTRICT OF COLUMBIA *ex rel.* ELISA DICKSON, RELATOR,**

**Plaintiffs**

**v.**

**BRISTOL MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S., L.L.C.; SANOFI-AVENTIS U.S., INC.; AND SANOFI-SYNTHELABO, INC. ,**

**Defendants.**

**FILED IN CAMERA & UNDER SEAL**

**JURY TRIAL DEMANDED**

**CIVIL ACTION NO. 11-cv-246-DRH-SCW**

COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 *et seq.*]; CALIFORNIA FALSE CLAIMS ACT [Cal. Gov. Code §12650 *et seq.*]; DELAWARE FALSE CLAIMS & REPORTING ACT [6 Del. C. §1201 *et seq.*]; DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. §1-1188.14 *et seq.*]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. §68.081 *et seq.*]; ILLINOIS WHISTLE BLOWER REWARD & PROTECTION ACT [740 ILCS § 175 *et seq.*]; HAWAII FALSE CLAIMS ACT [Haw. Rev Stat § 661-21(a)(3)] MONTANA FALSE CLAIMS ACT; [Mont. Code Ann. §17-/-410, Mont. Code Ann § 17-8-403]; INDIANA FALSE CLAIMS ACT AND WHISTLEBLOWERS PROTECTION ACT [Ind. Code Ann. §5-11-5.5-1-5-11-5.5-18]; MICHIGAN MEDICAID FALSE CLAIMS ACT [Mich. Comp Laws § 400.603,606 and 607]; NEW HAMPSHIRE FALSE CLAIMS ACT [New Hamp. Stat. 167:61-b]; MASSACHUSETTS FALSE CLAIMS ACT [Massachusetts Gen. Laws c.12 §5(A)]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat. Ann. § 27-14-1-27-14-15]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. §357.010 *et seq.*]; TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. §71-5-181 *et seq.*]; TEXAS MEDICAID FRAUD PREVENTION ACT [Tex. Human Res. Code, Ch. 36, §36.101 *et seq.*]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Stat. Ch. 842, Art. 19.1, §8.01-216.1 *et seq.*]; GEORGIA STATE MEDICAID ACT [Ga. Code 49-4-168 *et seq.*]; NEW YORK FALSE CLAIMS ACT [N.Y. St. Finance Law §187 *et* seq.]; CHICAGO FALSE CLAIMS ACT [Municipal Code of Chicago §1-22-010-§1-22-060]; NEW JERSEY FALSE CLAIMS ACT [N.J. STAT. § 2A:32C-1-17]; RHODE ISLAND FALSE CLAIMS ACT R.I. GEN. LAWS §9-1.1-1 -9.11-1.8; OKLAHOMA MEDICAID FALSE CLAIMS ACT 63 OKL. ST. §5053-5053.7; WISCONSIN STATUTE § 20.931 FOR FALSE CLAIMS FOR MEDICAL ASSISTANCE; NORTH CAROLINA FALSE CLAIMS ACT N.C. Gen. Stat. § 1-605-618, §108A-63; MINNESOTA FALSE CLAIMS ACT [Minn. Stat. §15C.01 *et. seq.*]; .]; the COLORADO MEDICAID FALSE CLAIMS ACT, C.R.S. §25.5-4-304, et seq.; the CONNECTICUT FALSE CLAIMS ACT, CHAPTER 319v Sec. 17b-301a et seq.; and the MARYLAND FALSE HEALTH CLAIMS ACT OF 2010, Subtitle 6, False Claims Against State Health Plans and State Health Programs, §2-601 *et seq.*

# FIRST AMENDED ORIGINAL COMPLAINT

Plaintiff-Relator Elisa Dickson ("Plaintiff-Relator"), through her undersigned attorneys, on behalf of the United States of America ("United States"), and the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Illinois, the State of Hawaii, the State of Indiana, the Commonwealth of Massachusetts, the State of Michigan, the State of New Mexico, the State of Montana, the State of New Hampshire, the State of New York, the State of Nevada, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of New Jersey, the State of Rhode Island, the State of Oklahoma, the State of Wisconsin, the State of North Carolina, the State of Minnesota, the State of Connecticut, the State of Colorado, the State of Maryland, the City of Chicago, and the District of Columbia (collectively, "the States and City"), for her First Amended Original Complaint against Defendants Bristol Myers Squibb Company; Sanofi-Aventis U.S., L.L.C.; Sanofi-Aventis U.S., Inc.; and Sanofi-Synthelabo, Inc., alleges as follows:

## I.
## INTRODUCTION

### A. Background Regarding BMS/Sanofi's Marketing of Plavix

1. Plavix® (clopidogrel bisulfate) ("Plavix") is a prescription blood thinner manufactured by Bristol-Myers Squibb Company ("BMS") and co-marketed in the United States by the Sanofi-Aventis Defendants ("Sanofi") (collectively "BMS/Sanofi"). Plavix is indicated for treatment of Acute Coronary Syndrome and use following a recent myocardial infarction or stroke or established peripheral artery disease.[1] Plavix is BMS's number one selling product.[2] For the quarter ending March 31, 2010, BMS reported gross revenue of $4.81 billion with Plavix

[1] *See* Plavix Package Insert at 1-2 and 5-6, attached hereto as Exhibit B ("Ex. B (Plavix Insert)").

sales accounting for over 30% of that total ($1.67 billion).[3] Plavix is scheduled to lose patent protection November 17, 2011.[4]

2. Defendants Sanofi and BMS have a marketing partnership under which they jointly market the prescription drug Plavix.[5] All efforts to promote Plavix are jointly administered by BMS/Sanofi. All Plavix advertisements, brochures, and promotional materials for Plavix feature both the BMS and Sanofi names.[6]

3. Plavix costs approximately $4.00 per pill, whereas aspirin costs approximately $0.04 per pill.[7] This action arises out of BMS/Sanofi's practice of promoting Plavix as a superior drug to aspirin for certain indicated usages, and charging approximately one hundred times more for Plavix than could be charged for aspirin, when in fact Plavix was no more effective than aspirin for certain indicated usages. BMS/Sanofi targeted such efforts at physicians and prescribers whose patients relied upon public assistance programs such as Medicaid, Medicare, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), and other federally-funded or Illinois-funded public assistance programs ("Government Payors"). BMS/Sanofi thereby caused physicians to submit many prescriptions for Plavix that resulted in

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[2] *See* Val Brickates Kennedy, *Bristol-Myers Profit Jumps as Plavix Sales Surge*, MARKETWATCH, April 29, 2010, attached hereto as Exhibit C.

[3] *Id.*

[4] *See* United States Food & Drug Admin. Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, *available at* http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm (last visited March 17, 2011).

[5] Plavix.com, Index, http://www.plavix.com/Index.aspx (last visited March 17, 2011) (indicating that the website is copyrighted to the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership).

[6] *See id.*

[7] Affidavit of Relator-Plaintiff Elisa Dickson ¶ 8, attached hereto as Exhibit A ("Ex. A (Affidavit)").

grossly inflated costs for Government Payors (and American and Illinois taxpayers) with no additional benefit to the covered patient, when compared to aspirin.

**B. FDA Regulatory Action Concerning the Promotion of Plavix**

4. On November 23, 1998, FDA's Division of Drug Marketing and Communications ("DDMAC") sent a letter ("the November 1998 Letter") to Defendant Sanofi concerning letters Defendant sent to physicians concerning the use of 300 mg of Plavix as a "loading dose" immediately prior to coronary stent placement.

5. At the time of the letter, the recommended dose of Plavix was 75 mg per day. The use of 300 mg of Plavix as a "loading dose" for coronary stent placement patients was neither proven to be safe or efficacious nor supported by substantial clinical evidence.

6. The November 1998 Letter concluded in relevant part:

> DDMAC is very concerned with the dissemination of the Letter because it states or suggests that Plavix is safe and effective in patients undergoing stent procedures, at an off-label dose, and in patients who will be concomitantly receiving other antiplatelet and/or anticoagulant agents. Further, no risk information was provided in the Letter to alert the reader to the adverse events associated with Plavix therapy. Because Plavix is associated with hemorrhagic adverse events at the recommended 75 mg/day dose, promotion of Plavix in patients receiving coronary artery interventions, at four times the recommended dose, in combination with other agents known to increase the risk of bleeding, raises significant patient safety concerns.

7. Consequently, FDA identified that Plavix "is associated with hemorrhagic adverse events at the recommended 75 mg/day dose" and identified that Defendant Sanofi's marketing efforts "rais(ed) significant patient safety concerns."

8. On May 9, 2001, DDMAC sent another letter to Defendant Sanofi objecting to its promotional efforts for Plavix and stated that the Defendant was "in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations."

9. DDMAC identified a Plavix sales aid, 69-201499, and stated that the sales aid contained "promotional claims that were false and misleading."

10. Specifically, DDMAC found that the sales aid overstated the efficacy of Plavix, made unsubstantiated superiority claims, constituted a misleading efficacy presentation and lacked fair balance.

11. Of particular importance is DDMAC's evaluation of Defendants' unsubstantiated claims concerning Plavix vis-à-vis aspirin which reads in relevant part:

**Unsubstantiated Superiority Claim**

On page 4 of the visual aid you present the claim, "Significant overall risk reduction vs. aspirin 325 mg in CAPRIE, a 3 year study of 19,185 patients." This claim is misleading because it suggests that Plavix is superior to aspirin when such has not been demonstrated by substantial evidence. As previously stated in our December 18, 1998, untitled letter, the CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superior efficacy over aspirin. Therefore, claims suggesting that Plavix is significantly better than aspirin are misleading because they are not based on substantial evidence.

12. Despite DDMAC's conclusion that "the CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superiority over aspirin," over ten years later Defendants nevertheless **continue** to promote that Plavix is superior to aspirin despite the fact that no study has generated evidence that supports that claim.

13. On March 26, 2009, DDMAC sent another letter to Defendant Sanofi after determining that Plavix internet advertisements misbranded Plavix and were "in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations."

14. DDMAC concluded that Sanofi failed to provide any risk information and stated in relevant part:

These sponsored links make representations and/or suggestions about the efficacy of PLAVIX, but fail to communicate **any** risk information. For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any claims made about the drug.

By omitting the most serious and frequently occurring risks associated with PLAVIX, the sponsored links misleadingly suggest that PLAVIX is safer than has been demonstrated.

**C. Medicaid and Medicare Part D Drug Utilization Review Requirements**

15. All federal government prescription programs require that a prospective drug utilization review ("DUR") be performed **before** the prescription is filled. The DUR is performed to ensure the beneficiary is not harmed by the drug. The DUR process includes a drug-drug interaction screen.

16. 42 U.S.C. §1396r-8(g)(1)(A)(i-iii) requires that states provide a drug review program in order to assure that Medicaid prescriptions are appropriate, medically necessary and:

> "are not likely to result in adverse medical results. The program shall be designed to educate physicians and **pharmacists** to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, **pharmacists**, and patients, or associated with specific drugs or groups of drugs, as well as **potential and actual severe adverse reactions** to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, **drug-drug interactions**, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and **clinical abuse/misuse**.

17. 42 U.S.C. §1396r-8(g)(2)(A)(i) provides:

> 2) Description of program
>
> Each drug use review program shall meet the following requirements for covered outpatient drugs:
>
> (A) Prospective drug review
>
> (i) The State plan shall provide for a review of drug therapy **before each prescription is filled or delivered to an individual receiving benefits under this subchapter**, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, **drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs)**, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

18. 42 CFR § 423.153(c)(4) requires that Medicare Part D sponsors have internal medication error and reduction measures and systems that address ways to reduce medication errors and adverse drug interactions, and improve medication use.

19. 42 CFR § 423.153(c)(5) requires that Part D sponsors provide CMS with information concerning the plan's quality assurance measures and systems to reduce medication errors and adverse drug interactions, and improve medication use.

20. All states allow a pharmacist to refuse to fill a prescription if, in his/her judgment, filling the prescription would compromise the safety of the patient.

21. For example, in New York NYS § 63.6 (b)(8)(ii)(d)(5) provides:

> 5. ***Nothing in this subparagraph shall prevent a pharmacist or pharmacy intern from refusing to dispense a prescription if, in his or her professional judgment, potential adverse effects, interactions or other therapeutic complications could endanger the health of the patient***.

22. For example, in Pennsylvania 6 Pa. Code § 27.18 (c) provides:

> (c) A pharmacist may decline to fill or refill a prescription if the pharmacist knows or has reason to know that it is false, fraudulent or unlawful, or that it is tendered by a patient served by a public or private third-party payor who will not reimburse the pharmacist for that prescription. A pharmacist may not knowingly fill or refill a prescription for a controlled substance or nonproprietary drug or device if the pharmacist knows or has reason to know it is for use by a person other than the one for whom the prescription was written, or will be otherwise diverted, abused or misused. In addition, **a pharmacist may decline to fill or refill a prescription if, in the pharmacist's professional judgment exercised in the interest of the safety of the patient, the pharmacist believes the prescription should not be filled or refilled. The pharmacist shall explain the decision to the patient. If necessary the pharmacist shall attempt to discuss the decision with the prescriber.**

23. For example, in New Jersey Section 45:14-66 of the New Jersey Pharmacy Act provides:

> 27. a. A pharmacist shall conduct a drug utilization review before each new medication is dispensed or delivered to a patient.

b. A pharmacist shall conduct a prospective drug utilization review in accordance with the provisions of this section before refilling a prescription or medication order to the extent he deems appropriate in his professional judgment.

c. ***A pharmacist shall exercise independent professional judgment as to whether or not to dispense or refill a prescription or medication order. In determining to dispense or refill a prescription or medication order, the decision of the pharmacist shall not be arbitrary but shall be based on professional experience, knowledge or available reference materials.***

24. For example, in Kansas KSA 65-1642 provides:

KSA 65-1642- ***Upon receipt of a prescription, the pharmacist shall examine the patients medication profile record before dispensing the medication to determine the possibility of harmful drug interaction or reaction to medication***. ***Upon recognizing the a potential harmful drug interaction or reaction to medication, the pharmacist shall take appropriate action to avoid or minimize the problem which shall, if necessary include consultation with the prescriber with documentation of actions taken on the prescription record***.

25. Texas law allows pharmacists to refuse to fill prescriptions if, in the opinion of the pharmacist, filling the prescription will compromise the patient's health. The Texas State Board of Pharmacy provides the following patient information:

***Is the pharmacist required to fill my prescription?***

Occasionally, **pharmacists may refuse to fill a prescription** if they believe that filling the prescription **is not in the best interest of your health**. Some of the reasons a pharmacist may refuse to fill a prescription include:

- **the pharmacist is concerned that the medication will interact badly with another drug you are taking**;

26. States are required to submit on an annual basis a "retrospective drug use review" of Medicaid beneficiary claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits. 42 U.S.C. §1396r-8(g)(2)(B) reads in its entirety:

B) **Retrospective drug use review**
The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b (r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records

> in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

27. On information and belief, BMS/Sanofi has known about the diminished anti-platelet effect of Plavix for patients who are poor CYP2C19 metabolizers since at least 2003 or earlier.

28. On information and belief, BMS/Sanofi has known about the diminished anti-platelet effect of Plavix when it is taken concomitantly with a drug known to inhibit the CYP2C19 enzyme since at least 2003 or earlier.

29. On March 25, 2010 FDA added a black box warning to the Plavix prescribing information.

30. The black box warning advised that Plavix does not have its anti-platelet effects until it is metabolized into its active form by the liver enzyme, CYP2C19.

31. Furthermore, the black box warning also advised that the use of Plavix **should be avoided** with drugs that are strong or moderate CYP2C19 inhibitors.

32. It is estimated that 2 percent to 14 percent of the U.S. population are poor metabolizers, and people of Asian and African ancestry have a greatly increased prevalence of poor CYP2C19 metabolizer status. Consequently, when a patient who is a CYP2C19 poor metabolizer takes Plavix, that patient receives no anti-platelet protection.

33. Researchers have found that patients who are CYP2C19 poor metabolizers have a 3.58 times greater risk for major adverse cardiovascular events such as death, heart attack, and stroke; the risk was greatest in CYP2C19 poor metabolizers.

34. Plavix prescriptions are written to help prevent the occurrence of heart attack or stroke. If the efficacy of a Plavix prescription is compromised, the patient is put in serious jeopardy for a heart attack or stroke.

35. In fact, FDA stated that:

> For Plavix to work, enzymes in the liver (particularly CYP2C19) must convert (metabolize) the drug to its active form. Patients who are poor metabolizers of the drug, do not effectively convert Plavix to its active form. In these patients, Plavix has less effect on platelets, and therefore less ability to prevent heart attack, stroke, and cardiovascular death. It is estimated that 2 to 14% of the population are poor metabolizers; the rate varies based on racial background."

36. Proton pump inhibitors like esomeprazole (Nexium), omeprazole (Prilosec) and lansoprazole (Prevacid) are strong CYP2C19 inhibitors and seriously diminish, if not completely eradicate, Plavix's anti-platelet activity.

37. Prior to this warning, the vast majority of Plavix prescriptions filled with esomeprazole and lansoprazole were filled.

38. For example, in Texas from October 1, 2008 through September 30, 2009, the following drug drug interaction reports were recorded for Plavix and esomeprazole and Plavix and lansoprazole:

**Texas Health and Human Services Commission**
**Medicaid FED_YTD DUR Report for Top 200 Drugs for Alert DD**
**For Claims Processed Between 10/01/2008 and 9/30/2009**

| Rank | Ajudicated Drug History Drug | DD Alert Occurrences | DD Claims for Drug | %DD Claims for Drug | DD Claims Reversed | %DD Claims Reversed | Total Adjudicated Claims for Drug |
|---|---|---|---|---|---|---|---|
| 122 | ESOMEPRAZOLE MAG TRIHYDRATE | 4,595 | 4,479 | 1.77% | 144 | 0.06% | 253,245 |
| | CLOPIDOGREL BISULFATE | 3,541 | | | | | |
| 139 | LANSOPRAZOLE | 3,714 | 3,631 | 1.89% | 187 | 0.10% | 191,901 |
| | CLOPIDOGREL BISULFATE | 3,424 | | | | | |

39. Prior to the FDA mandated label change and despite the drug alert, 99.94% of all prescriptions for Plavix and esomeprazole were nevertheless filled.

40. Prior to the FDA mandated label change and despite the drug alert, 99.9% of all prescriptions for Plavix and lansoprazole were nevertheless filled.

41. None of 6,965 Medicaid beneficiaries identified in this report received the requisite anti-platelet activity necessary to protect them.

42. When a Plavix prescription is filled concomitantly with a proton pump inhibitor for a Medicaid beneficiary, the Medicaid beneficiary receives no anti-platelet protection. Consequently, each time Medicaid paid for a Plavix prescription that was filled with a proton pump inhibitor, or any drug that inhibits the enzyme CYP2C19, the beneficiary receives diminished, if any, anti-platelet activity and the Medicaid program is thus defrauded out of the cost of the Plavix prescription.

43. When a Plavix prescription is filled for Medicaid beneficiary who is a poor CYP2C19 metabolizer, the Medicaid beneficiary receives no anti-platelet protection. Consequently, each time Medicaid paid for a Plavix prescription that was filled for a person who is a poor CYP2C19 metabolizer, the beneficiary receives diminished, if any, anti-platelet activity and the Medicaid program is thus defrauded out of the cost of the Plavix prescription.

44. Prior to the FDA's insertion of the Black Box warning into Plavix's prescribing information, any time Plavix was prescribed concomitantly with a drug known to inhibit cytochrome CYP2C19 and the Plavix prescription was paid for by government funds, a false claim has been submitted because, had the government payors, pharmacists or physicians known of this grave risk, approval would never have been granted for the payment of the Plavix prescription.

45. Prior to the FDA's insertion of the Black Box warning into Plavix's prescribing information, any time Plavix was prescribed for patients who were poor CYP2C19 metabolizers

and such prescription was paid for by government funds, a false claim has been submitted because, had the government payors, pharmacists or physicians known of this grave risk, approval would never have been granted for payment for the prescription.

**D. Regulations Governing the Content of Drug Labeling**

46. There are numerous regulations governing the content of drug labeling. One regulation, 21 CFR 201.57(e), is especially relevant to Plaintiff-Relator's allegations. The regulation imposes an affirmative duty on a manufacturer to revise a drug's labeling once there is a "reasonable association of a serious hazard with a drug".

47. The regulation reads in its entirety:

> Warnings. **Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved**. A specific warning relating to a use not provided for under the Indications and Usage section of the labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the Adverse Reactions section of the labeling.

48. From 2003 onwards, Defendants had full knowledge that the concomitant use of Plavix with strong or moderate CYP2C19 inhibitors would severly compromise, if not eliminate, Plavix's anti-platelet activity, yet failed to amend their label to reflect this information.

49. From 2003 onwards, Defendants had full knowledge that Plavix provided little to no anti-platelet protection for poor CYP2C19 metabolizers yet failed to amend their label to reflect this information.

50. Because Plavix is taken by patients who need anti-platelet protection, the dangers posed by the concomitant use of Plavix with strong or moderate CYP2C19 inhibitors represent both a clear "potential safety hazard" and "serious hazard" anticipated by 21 CFR 201.57(e).

51. Yet 21 C.F.R. 201.57(e) is not the only regulation that imposed an affirmative duty on Defendants to strengthen Plavix's labeling. Known as the "Changes Being Effected" regulation, 21 C.F.R. §314.70(c)(6)(iii) allows drug manufacturers to strengthen safety language without FDA approval.

52. 21 C.F.R. §314.70(c)(6)(iii) reads in its entirety:

> (6) The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug product involved upon receipt by the agency of a supplement for a change.
>
> These changes include, but are not limited to: (i) Addition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess; (ii) A change in the size and/or shape of a container for a nonsterile drug product, except for solid dosage forms, without a change in the labeled amount of drug product or from one container closure system to another; **(iii) Changes in the labeling to accomplish any of the following:** (**A) To add or strengthen a contraindication, warning, precaution, or adverse reaction; (B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage; (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product**; (D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or (E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

53. Writing for the majority in the Supreme Court case Wyeth v. Levine, 555 U.S. 1 (2009), Justice Stevens opined on the issue of whether a manufacturer has an affirmative duty to amend a drug's label once new safety information is available:

> Wyeth's cramped reading of the CBE regulation and its broad reading of the FDCA's misbranding and unauthorized distribution provisions are premised on a more fundamental misunderstanding. Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. See, *e.g.*, 21 CFR §201.80(e) (requiring a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); §314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed. Reg. 49605 ("Manufacturers continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information").

54. Furthermore, Justice Stevens addressed the issue of whether manufacturer's have "superior access to information about their drugs" vis-à-vis the FDA stating:

> In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market,[11] and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.

55. Consequently, a manufacturer should, without FDA approval, amend a drug's labeling to add or strengthen a contraindication, warning, precaution or adverse reaction, to add

or strengthen a statement about drug abuse, dependence, psychological effect or overdosage or to add or strengthen an instruction about dosage and administration intended to increase safe use of the drug as soon as the manufacturer has knowledge of "new risks" associated with the drug.

56. In failing to amend the Plavix label to reflect the dangers posed by concomitant use of Plavix with moderate or strong CYP2C19 inhibitors and/or patients who are poor CYP2C19 metabolizers **when it knew of the risks associated with such usages**, Defendants are in violation of the applicable statutes, regulations and written directives of the Medicare, Medicaid, Federal health programs and the Food and Drug Administration.

57. Consequently, each and every Plavix prescription written by a physician, and subsequently filled by a pharmacist, for a patient also taking a moderate or strong CYP2C19 inhibitor and/or a patient who is poor CYP2C19 metabolizer, a false claim has been submitted to the government.

**E. Relator Dickson's Knowledge of BMS/Sanofi's Scheme to Defraud the Government**

58. BMS and Sanofi have knowingly participated in a comprehensive scheme to defraud federal and state governments while illegally and deceptively promoting Plavix to further increase Plavix sales.

59. The Relator, Elisa Dickson ("Dickson"), has worked in the pharmaceutical industry for approximately twelve years and is currently a sales representative who specializes in selling Plavix.[8] She has direct and independent knowledge of the information on which the allegations are based.[9] Dickson began working for BMS in 1999.[10] Dickson took a position as a

[8] *See* Ex. A (Affidavit).
[9] *See id.*
[10] *Id.* at ¶ 3.

sales representative at Sanofi in 2003.[11] Her duties included selling Plavix, in addition to other drugs.[12] From 2008 to 2010, Dickson's primary sales efforts were concentrated on selling Plavix to primary care physicians (family practice, general practice and internal medicine) to prevent ischemic strokes in patients who have experienced a recent stroke and for the reduction of atherothrombotic events in patients with established Peripheral Arterial Disease, recent stroke, recent myocardial infarction, or acute coronary syndrome.[13] Dickson remains employed at Sanofi.[14]

60. Dickson's initial training for selling Plavix consisted of several weeks of both home study and classroom training in St. Louis, Missouri in September 2003.[15] Her training did not focus upon Plavix, but also included other drugs.[16] In 2008, Dickson attended a two day refresher course on Plavix in Dallas, Texas.[17] This training was limited and did not provide thorough background and knowledge on the Plavix studies that had been published since 2006 such as the Aggrenox study PRoFESS.[18]

61. Plavix is a major producer of revenue and market share for BMS/Sanofi. For example, according to marketing data Dickson received from Sanofi, Plavix is prescribed for approximately 31% of patients who have experienced a recent stroke.[19] Prescriptions of Plavix

[11] *Id.* at ¶ 4.
[12] *Id.*
[13] *Id.* at ¶ 5.
[14] *Id.* at ¶¶ 4-5.
[15] *Id.* at ¶ 6.
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.* at ¶ 9.

for recent stroke victims generate approximately $666 Million in annual sales for Sanofi (roughly 10% of an estimated $7 Billion in total annual Plavix sales).[20]

***i. BMS/Sanofi's False Statements Regarding Plavix***

62. As a member of the sales force, Dickson was instructed by Sanofi and, based on these instructions, regularly promoted Plavix having certain characteristics that BMS/Sanofi knew were not true.[21]

63. For instance, despite the non-significant efficacy data in certain trials for stroke patients, Sanofi instructed Dickson to promote Plavix as being superior to aspirin in stroke patients.[22] Also, company sales pamphlets citing these trials claimed that there was "proven efficacy" of Plavix over aspirin in ischemic stroke patients.[23] In fact, Sanofi required that Dickson promote Plavix as comparably safe to aspirin based on one study even though that study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today.[24] Dickson was also instructed to encourage physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin.[25]

64. Dickson was instructed to present the data from yet another study in a manner designed to confuse physicians and make them believe that Aggrenox (aspirin + dipyridamole) was inferior to Plavix.[26] Rather than state that the study showed no difference between the two drugs, Dickson was instructed to emphasize that "Aggrenox failed to achieve the primary

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[20] *Id.*
[21] *See* Ex. A (Affidavit).
[22] *Id.* at ¶ 16-18.
[23] *Id.* at ¶ 16; *see The Efficacy and Safety of PLAVIX in Ischemic Stroke Patients – A Case-Based Approach*, attached hereto as Exhibit D, at 4 ("Ex. D (Efficacy and Safety of PLAVIX)").
[24] Ex. A (Affidavit) at ¶ 22.
[25] *Id.* at ¶ 19.
[26] *Id.* at ¶ 31.

endpoint of non-inferiority for recurrent stroke in stroke patients" and further that "major hemorrhagic events and intracranial bleeds were observed more frequently in the Aggrenox group."[27] She was to also instructed to state that "it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients."[28] The purpose of talking to physicians about this particular trial was to increase Plavix's market share.[29]

65. In addition to misrepresenting or withholding certain studies, Dickson was instructed by Sanofi to focus sales calls on physicians who wrote significant numbers of prescriptions for patients covered by certain Government Payors.[30] According to Dickson, the purpose of targeting such patients was that there was less resistance by physicians to prescribing expensive drugs due to the fact that the government was paying for the medication rather than the patient.[31]

***ii. BMS/Sanofi's Comprehensive Scheme to Defraud the Government***

66. Dickson's experience at BMS and Sanofi demonstrates BMS/Sanofi's comprehensive scheme to defraud federal and state governments while illegally and deceptively promoting Plavix to further increase Plavix sales. In particular, BMS/Sanofi manipulated clinical trial data to support fraudulent claims regarding Plavix's efficacy relative to cheaper alternatives, such as aspirin. BMS/Sanofi mischaracterized clinical studies which contradicted the sales campaign. While promoting this false narrative regarding Plavix efficacy compared to cheaper alternatives like aspirin, BMS/Sanofi targeted doctors whose patients rely on

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[27] *Id.*; *Summary of PRoFESS (Prevention Regimen for Effectively Avoiding Second Strokes)*, attached hereto as Exhibit E ("Ex. E (PRoFESS Summary)"), at 5.
[28] Ex. A (Affidavit) at ¶ 31; Ex. E (PRoFESS Summary) at 5.
[29] Ex. A (Affidavit) at ¶ 33.
[30] *Id.* at ¶ 34.
[31] *Id.* at ¶ 35.

Government Payors for health care treatment so as to wrongfully inflate sales and profits at a tremendous cost to American taxpayers.

## II.
## PARTIES

67. Relator Dickson is a citizen of the United States of America ("United States"). Relator is currently a resident of the State of Arkansas.

68. Defendant Bristol-Myers Squibb Company ("BMS") is incorporated in the state of Delaware with its corporate headquarters in New York, New York. BMS is doing business in the Southern District of Illinois and has violated the False Claims Act, Illinois Whistleblower Reward and Protection Act, and Illinois Public Assistance Fraud Act in the Southern District of Illinois. Defendant may be served through its registered agent CT Corporation System, 111 Eighth Avenue, New York, New York 10011.

69. Defendant Sanofi-Aventis U.S., L.L.C. is a Delaware corporation doing business in New Jersey. Sanofi-Aventis U.S., L.L.C. is doing business in the Southern District of Illinois and has violated the False Claims Act, Illinois Whistleblower Reward and Protection Act, and Illinois Public Assistance Fraud Act in the Southern District of Illinois. Defendant may be served through its registered agent, Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628.

70. Defendant Sanofi-Aventis U.S., Inc. is a Delaware corporation doing business in New Jersey. Sanofi-Aventis U.S., Inc. is doing business in the Southern District of Illinois and has violated the False Claims Act, Illinois Whistleblower Reward and Protection Act, and Illinois Public Assistance Fraud Act in the Southern District of Illinois. Defendant may be served through its registered agent, Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628.

71. Defendant Sanofi-Synthelabo, Inc. is a Delaware corporation doing business in New Jersey. Sanofi-Synthelabo, Inc. is doing business in the Southern District of Illinois and has violated the False Claims Act, Illinois Whistleblower Reward and Protection Act, and Illinois Public Assistance Fraud Act in the Southern District of Illinois. Defendant may be served through its registered agent, Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628.

72. Collectively, Defendant Sanofi-Aventis U.S., L.L.C., Defendant Sanofi-Aventis U.S., Inc., and Defendant Sanofi-Synthelabo, Inc. are referred to as "Sanofi."

## III.
## JURISDICTION AND VENUE

73. Jurisdiction and venue are proper in this Court for the following reasons:

a. Any action under Section 3730 of the False Claims Act may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by Section 3729 occurred.[32] Additionally, the district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under Section 3730.[33] Therefore, jurisdiction for this Court exists pursuant to the False Claims Act (31 U.S.C. § 3730(b)(1) and 31 U.S.C. § 3732(a) and (b)) because Dickson's claims seek remedies on behalf of the United States and the State of Illinois for Defendants' multiple violations of 31 U.S.C. § 3729, 740 ILCS 175, and 305 ILCS 5/8A-1, *et seq.*, some of which occurred in the Southern

[32] 31 U.S.C. § 3732(a).
[33] *Id.* at § 3732(b).

District of Illinois and because the Defendants transact other business within the Southern District of Illinois. This Court also has jurisdiction over this case pursuant to 28 U.S.C. § 1331.

b. Venue is proper in this Court pursuant to 31 U.S.C. § 3730(b)(1) and 31 U.S.C. § 3732(a) because Defendants are qualified to do business in the State of Illinois and conduct business within the State of Illinois and within the Southern District, and at least one of the Defendants transacts business or committed acts proscribed by 31 U.S.C. § 3729, 740 ILCS 175, and 305 ILCS 5/8A-1, *et seq.*, in the Southern District of Illinois. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Illinois governments while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Illinois and specifically within the Southern District of Illinois. Over 40% of nationwide Plavix sales are covered by Government Payors. Illinois is the fifth most populous state in the United States. A substantial percentage of Plavix sales in the Southern District of Illinois are covered by Government Payors.

## IV.
## STATUTORY BACKGROUND

74. Plavix is a prescription blood thinner manufactured by BMS and co-marketed in the United States by BMS/Sanofi.

### A. False Claims Act

75. This is an action to recover damages and civil penalties on behalf of the United States and Relator Elisa Dickson arising from false or fraudulent statement, claims, and acts by Defendants made in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733. As detailed in Dickson's testimony, BMS/Sanofi promoted Plavix as a superior drug to aspirin for certain indicated usage and charged approximately one hundred times more for Plavix than could be charged for aspirin, when in fact Plavix was no more effective than aspirin for certain indicated

usages. BMS/Sanofi focused their efforts among doctors whose patient populations were composed of Government Payor subscribers. BMS/Sanofi's conduct caused physicians to submit many prescriptions for Plavix that resulted in grossly inflated costs for Government Payors with no additional benefit to the covered patient, when compared to aspirin.

76. For conduct occurring before May 20, 2009, the False Claims Act provides in pertinent part that:

> (a) Any person who
>
> > (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
> >
> > (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
> >
> > (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; [or]
> >
> > ****
> >
> > (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government
>
> is liable to the Government for a civil penalty of not less than $5,000 and not more than $10,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.[34]

77. For conduct occurring on or after May 20, 2009, the False Claims Act provides that any person who:

> > (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

[34] *See* History to 31 U.S.C. § 3729 (providing text prior to May 20, 2009 amendments).

> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
>
> ****
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.[35]

78. The False Claims Act allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in federal district court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730. Based on these provisions, Dickson, on behalf of the United States Government, seeks through this action to recover damages and civil penalties arising from BMS/Sanofi's false and/or fraudulent conduct in connection with its false statements regarding efficacy. Dickson believes that the United States has suffered significant damages as a result of the BMS/Sanofi's false and/or fraudulent conduct.

**C. Illinois Whistleblower Reward and Protection Act**

79. This is an action to recover damages and civil penalties on behalf of the State of Illinois and Relator Elisa Dickson arising from false or fraudulent statement, claims, and acts by Defendants made in violation of the Illinois Whistleblower Reward and Protection Act, 740

ILCS 175. As detailed in Dickson's testimony, BMS/Sanofi promoted Plavix as a superior drug to aspirin for its indicated usage and charged approximately one hundred times more for Plavix than could be charged for aspirin, when in fact Plavix was no more effective than aspirin for the indicated usages. In Illinois, BMS/Sanofi focused their efforts among doctors whose patient populations were composed of Government Payor subscribers. BMS/Sanofi's conduct caused physicians to submit many prescriptions for Plavix that resulted in grossly inflated costs for Government Payors with no additional benefit to the covered patient, when compared to aspirin. Such actions by BMS/Sanofi are in contravention of Illinois law.

80. The Illinois Whistleblower Reward and Protection Act provides in pertinent part that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
>
> ****
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State,

is liable to the State for a civil penalty of not less than $5,500 and not more than $11,000, plus three times the amount of damages which the State sustains because of the act of that person.[36]

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[35] 31 U.S.C. § 3729(a).
[36] 740 ILCS 175/3(a)(1).

A person violating this subsection shall also be liable to the State for the costs of a civil action brought to recover any such penalty or damages.[37]

81. The Illinois Whistleblower Reward and Protection Act allows any persons having knowledge of a false or fraudulent claim against the State of Illinois to bring an action for themselves and for the State of Illinois and to share in any recovery as authorized by 740 ILCS 175/4(d). Based on these provisions, Dickson, on behalf of the State of Illinois, seeks through this action to recover damages and civil penalties arising from BMS/Sanofi's false and/or fraudulent conduct in connection its false statements regarding efficacy within Illinois. Dickson believes that the State of Illinois has suffered significant damages as a result of the BMS/Sanofi's false and/or fraudulent conduct within Illinois.

**D. Illinois Public Assistance Fraud Act**

82. This is an action to recover damages and civil penalties on behalf of the State of Illinois and Relator Elisa Dickson arising from false or fraudulent statement, claims, and acts by Defendants made in violation of the Illinois Public Assistance Fraud Act, 305 ILCS 5/8A-1, *et seq*. As detailed in Dickson's testimony, BMS/Sanofi have promoted Plavix as a superior drug to aspirin for its indicated usage and charged approximately one hundred times more for Plavix than could be charged for aspirin, when in fact Plavix was no more effective than aspirin for certain indicated usages. In Illinois, BMS/Sanofi focused their efforts among doctors whose patient populations were composed of Government Payor subscribers. BMS/Sanofi's conduct caused physicians to submit many prescriptions for Plavix that resulted in grossly inflated costs for Government Payors with no additional benefit to the covered patient, when compared to aspirin. Such actions by BMS/Sanofi are in contravention of Illinois law.

[37] *Id.* at 175/3(a)(2).

83. The Illinois Public Assistance Fraud Act provides in pertinent part that:

> (b) any person, firm, corporation, association, agency, institution or other legal entity that willfully, by means of a false statement or representation, or by concealment of any material fact or by other fraudulent scheme or device on behalf of himself or others, obtains or attempts to obtain benefits or payments under this Code to which he or it is not entitled, or in a greater amount than that to which he or it is entitled,

shall be liable for repayment of any excess benefits or payments received and, in addition to any other penalties provided by law, civil penalties consisting of (1) the interest on the amount of excess benefits or payments at the maximum legal rate in effect on the date the payment was made to such person, firm, corporation, association, agency, institution or other legal entity for the period from the date upon which payment was made to the date upon which repayment is made to the State, (2) an amount not to exceed three times the amount of such excess benefits or payments, and (3) the sum of $2,000 for each excessive claim for benefits or payments.[38]

84. Further, the Illinois Public Assistance Fraud Act provides that any person who commits the offense of vendor fraud or recipient fraud as defined in Section 8A-2 and Section 8A-3 of this Article shall forfeit any monies, profits or proceeds, and any interest or property which the Court determines he has acquired or maintained, directly or indirectly, in whole or in part as a result of such offense.[39] Such person shall also forfeit any interest in, securities of, claim against, or contractual right of any kind which affords him a source of influence over, any enterprise which he has established, operated, controlled, conducted, or participated in conducting, where his relationship to or connection with any such thing or activity directly or indirectly, in whole or in part, is traceable to anything or benefit which he has obtained or acquired through vendor fraud or recipient fraud.[40]

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[38] 305 ILCS 5/8A-7.
[39] *Id.*
[40] *Id.*

**E. There are No Bars to Recovery**

85. None of the False Claims Act Section 3730(e) bars to recovery apply to Dickson or, in the alternative, Dickson is an original source as defined therein.[41] Dickson has direct and independent knowledge of the information on which the allegations are based.[42] As required pursuant to 31 U.S.C. §§ 3730(b) and (e), Dickson has voluntarily provided information, oral and/or written, and has sent disclosure statement(s) of all material evidence, information, and documents related to this complaint, both before and contemporaneously with filing, to the Attorney General of the United States and the United States Attorney for the Southern District of Illinois. Further, the "related action" bar does not apply to Dickson.[43]

86. None of the Illinois Whistleblower Reward and Protection Act Section 175/4(e) bars to recovery applies to Dickson or, in the alternative, Dickson is an original source as defined therein.[44] Dickson has direct and independent knowledge of the information on which the allegations are based.[45] As required pursuant to 740 ILCS 175/4(b), Dickson has voluntarily provided a copy of the Complaint and written disclosure of substantially all material evidence and information she possesses contemporaneously with filing this Complaint to the State of Illinois.

87. To the extent, if any, that this case is deemed to be a related action and that facts set forth herein are deemed to be the same as facts underlying an existing qui tam False Claims Act action pending at the time of filing of this action, as prohibited in 31 U.S.C. § 3730 (e)(3), said factual allegations in common with either pending action, which would cause this to be a

[41] *See id.* at § 3730(e)(4)(B).
[42] *See* Ex. A (Affidavit).
[43] *See* 31 U.S.C. § 3730(b)(5).
[44] *See id.* at § 3730(e)(4)(B).
[45] *See* Ex. A (Affidavit).

related cause of action, are hereby expressly excluded from this action, but only to the limited extent necessary to exclude such preemption.

88. Furthermore, to the extent that the court finds that the allegations or transactions set forth herein are based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the United States is already a party, if any such proceedings exist, then the allegations or transactions referred to herein that the court deems are based upon allegations or transactions which are the subject of any such civil suit or administrative civil, money penalty proceeding are expressly excluded, but only for the specific time periods, specific companies, and specific allegations or transactions as necessary.

## V.
## FACTUAL ALLEGATIONS

89. BMS/Sanofi have acted in a comprehensive scheme to defraud federal and state governments while illegally and deceptively promoting Plavix to further increase Plavix sales. BMS/Sanofi's scheme involved false statements misrepresenting Plavix's efficacy compared to cheaper alternatives such as aspirin.

### A. BMS/Sanofi manipulated clinical trial data to support fraudulent claims regarding Plavix's efficacy compared to cheaper alternatives such as aspirin.

90. BMS/Sanofi improperly lumped together different patient trial groups to support a claim of superiority over aspirin, an exponentially cheaper alternative.[46] For example, Plavix is indicated for treatment of patients who have recently suffered from stroke.[47] Plavix's indication for patients with recent stroke was obtained based on the *Clopidogrel [Plavix] vs. Aspirin in Patients at Risk for Ischemic Events* ("CAPRIE") clinical trial.[48] The CAPRIE trial enrolled

[46] *See id.*

[47] Ex. B (Plavix Insert) at 2.

[48] *See* CAPRIE Trial Abstract, attached hereto as Exhibit F ("Ex. F (CAPRIE)"); s*ee also* CAPRIE Steering Committee, *A randomised, blinded, trial of clopidogrel versus aspirin in*

19,185 patients with approximately 6,300 patients in each of three different subgroups.[49] The three subgroups included (a) patients who experienced a recent stroke, (b) patients who experienced recent myocardial infarction (MI), and (c) patients who experienced symptomatic peripheral arterial disease (PAD).[50] In each subgroup, half of the patients were given 325 mg of aspirin once daily and the other half were given 75 mg of Plavix daily. [51]

91. The primary efficacy endpoint for the trial was the combination of ischemic stroke, MI, or vascular death.[52] Put another way, in each of the three subgroups the trial compared the combined rates of ischemic stroke, myocardial infarction, and vascular death between patients receiving Plavix against those receiving aspirin to determine whether Plavix was more or less effective in preventing those events, i.e. ischemic stroke, MI, and vascular death.[53] In the CAPRIE trial, Plavix demonstrated a marginally significant 8.7% relative risk reduction of the primary endpoint compared to aspirin.[54] The absolute risk reduction was 0.5%, meaning that for every 1,000 patients treated with Plavix only five patients benefited from Plavix treatment as compared to aspirin treatment.[55]

92. The CAPRIE composite data was driven primarily by the peripheral arterial disease (PAD) subgroup which showed a relative risk reduction of 23.8% in the primary

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*patients at risk of ischaemic events (CAPRIE),* THE LANCET, Vol. 348, Issue 9038, Nov. 16, 1996.

[49] *See* Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra*.

[50] *See* Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra*.

[51] *See* Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra*; Ex. A (Affidavit) at ¶¶ 10-11.

[52] *See* Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra*; Ex. A (Affidavit) at ¶ 11.

[53] Ex. A (Affidavit) at ¶ 12.

[54] Ex. F (CAPRIE); s*ee also* CAPRIE Steering Committee, *supra*; Ex. A (Affidavit) at ¶ 12.

[55] Ex. A (Affidavit) at ¶ 12.

endpoint.[56] However, in the recent stroke and recent myocardial infarction subgroups, CAPRIE demonstrated that there was no statistically significant reduction in the primary endpoint for patients taking Plavix as compared to patients taking aspirin.[57] Indeed, in the case of aspirin, even though no statistically significant reduction existed favoring aspirin over Plavix for recent myocardial infarctions, the study concluded the trend favored aspirin over Plavix.[58] This subgroup information was included in the CAPRIE Road Map.[59] The CAPRIE Road Map was created by Sanofi and used only for internal sales training.[60] It was not to be used in sales presentations to doctors.[61] On pamphlets provided to physicians summarizing the CAPRIE study, the subgroup analysis was not provided.[62] Only the overall 8.7% reduction in the primary endpoint was provided.[63] The subgroup analysis would have demonstrated that in two of the three subgroups (recent stroke and recent myocardial infarction patients) Plavix failed to reduce instances of ischemic stroke, MI, or vascular death any more than simple treatment with aspirin.[64]

93. Despite the non-significant efficacy data in the CAPRIE trial for stroke patients, company sales pamphlets (citing CAPRIE) claimed that there was "proven efficacy" of Plavix

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[56] *Id.* at ¶ 13.

[57] *Id.* at ¶ 14; *see* CAPRIE Road Map, attached hereto as Exhibit G ("Ex. G (CAPRIE Road Map)").

[58] CAPRIE Road Map, attached hereto as Exhibit G ("Ex. G (CAPRIE Road Map)").

[59] Ex. A (Affidavit) at ¶ 15; Ex. G (CAPRIE Road Map).

[60] Ex. A (Affidavit) at ¶ 15; Ex. G (CAPRIE Road Map) at 1 (stating "For Sales Training Only; Not to be Used in Selling Presentations").

[61] Ex. A (Affidavit) at ¶ 15; Ex. G (CAPRIE Road Map) at 1 (stating "For Sales Training Only; Not to be Used in Selling Presentations").

[62] Ex. A (Affidavit) at ¶ 15; *see, e.g.*, Ex. D (Efficacy and Safety of PLAVIX).

[63] Ex. A (Affidavit) at ¶ 15; *see* Ex. D (Efficacy and Safety of PLAVIX) at 4.

[64] Ex. A (Affidavit) at ¶ 15; Ex. G (CAPRIE Road Map).

over aspirin in ischemic stroke patients.[65] This claim was rebutted when in 2010 the ASA's *Guidelines for the Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack* were amended to state that, "No studies have compared clopidogrel with placebo, and studies comparing it with other antiplatelet agents have not clearly established that it is superior or even equivalent to any one of them."[66]

94. The 2010 ASA guidelines recommend the use of Plavix for the treatment of stroke patients only if the patients are allergic to aspirin.[67] The 2010 ASA guidelines provide a Class I; Level of Evidence A recommendation for the use of Aspirin in the secondary prevention of stroke.[68] The guidelines only provide a Class IIA, Level of Evidence B recommendation for the use of Plavix in the secondary prevention of stroke.[69] Class I means that a treatment should be administered.[70] Class IIA means that additional studies with focused objectives are needed, but that it is reasonable to administer treatment.[71] Regardless, BMS/Sanofi ordered its sales personnel to promote Plavix as being superior to aspirin in stroke patients.[72] As a result, Plavix was regularly and systematically presented to physicians as superior to aspirin for treatment of stroke patients.[73]

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[65] Ex. A (Affidavit) at ¶ 16; *see* Ex. D (Efficacy and Safety of PLAVIX) at 4.

[66] Karen L. Furie et al, *Guidelines for the Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack*, at 248, attached hereto as Exhibit H ("Ex. H (ASA Guidelines)") and available at http://stroke.ahajournals.org/cgi/content/full/42/1/227 (last visited March 18, 2011); *see also* Ex. A (Affidavit) at ¶ 16.

[67] Ex. H (ASA Guidelines) at 249.

[68] Ex. A (Affidavit) at ¶ 17.

[69] *Id.*

[70] *Id.*

[71] *Id.*

[72] *Id.* at ¶ 18.

[73] *Id.*

95. BMS/Sanofi also encouraged physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin.[74] According to ASA, however, "there have been no clinical trials to indicate that switching anti-platelet agents reduces the risk for subsequent events."[75]

**B. BMS/Sanofi fraudulently downplayed and misrepresented specific and known health risks of Plavix use compared to cheaper alternatives such as aspirin.**

96. The CAPRIE trial also showed that there was less gastrointestinal bleeding in patients taking Plavix compared to aspirin.[76] However, the aspirin dose used in CAPRIE was 325 mg per day for all patients.[77] Presently, physicians recommend an aspirin dose of as little as 50 mg per day, which is equally effective but minimizes the bleeding risk.[78] BMS/Sanofi ordered its sales force to promote Plavix as comparably safe to aspirin based on the CAPRIE study even though the CAPRIE study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today.[79]

97. CAPRIE was published in 1996.[80] Following this study, BMS/Sanofi has not further tested Plavix against aspirin to determine whether a more commonly prescribed (i.e. lower) dose of aspirin supports BMS/Sanofi's claims that Plavix imposes a lower risk of gastrointestinal bleeding when compared to aspirin (as its used in a therapeutic context).[81] However, in a study published in the January 20, 2005 New England Journal of Medicine (the "Chan Study"), Plavix was shown to cause significantly more gastrointestinal bleeding than aspirin plus esomeprazole (brand name Prilosec) in patients with a history of aspirin-induced

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[74] *Id.* at ¶ 19.
[75] Ex. H (ASA Guidelines) at 248; *see also* Ex. A (Affidavit) at ¶ 20.
[76] Ex. F (CAPRIE); *see also* Ex. A (Affidavit) at ¶ 21.
[77] Ex. F (CAPRIE); *see also* Ex. A (Affidavit) at ¶ 21.
[78] *See, e.g.*, Ex. A (Affidavit) at ¶ 21.
[79] *Id.* at ¶¶ 21-22.
[80] *See* CAPRIE Steering Committee, *supra* (published November 16, 1996).

ulcers.[82] The Chan Study showed that switching patients to Plavix if they have ulcers with aspirin is not safe, and that it would be cheaper to simply add esomeprazole (an inexpensive over the counter medication) to aspirin.[83] The results of the Chan Study were not disclosed to prescribing neurologists.

**C. BMS/Sanofi mischaracterized clinical studies which contradicted the sales campaign.**

98. Aggrenox (aspirin + dipyridamole) is also recommended over Plavix for stroke patients in the 2010 ASA Guidelines.[84] The efficacy and safety of Aggrenox versus aspirin is supported by three large clinical trials, whereas only one clinical trial (CAPRIE) compares Plavix with aspirin.[85] The *Prevention Regimen for Effectively Avoiding Second Strokes* ("PRoFESS") trial compared Aggrenox with Plavix in the prevention of secondary stroke in patients who have experienced a recent stroke.[86]

99. According to the ASA, the PRoFESS trial "showed no difference in stroke recurrence among patients assigned to [Plavix] compared with patients assigned to [Aggrenox]."[87] There was also no statistically significant difference between the two drugs in causing major hemorrhagic events.[88] However, BMS/Sanofi presented the PRoFESS data in a manner designed to confuse physicians and enforce an unsupported believe that Aggrenox was inferior to Plavix.[89]

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[81] Ex. A (Affidavit) at ¶ 23.
[82] Francis Chan, *Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding*, 352 N. ENGL. J. MED. 3 at 241-243 (2005), attached hereto as Exhibit I ("Ex. I (Chan Study)").
[83] *See* Ex. I (Chan Study); Ex. A (Affidavit) at ¶ 24.
[84] *Id.* at ¶ 25.
[85] *Id.* at ¶ 26.
[86] Ex. E (PRoFESS Summary).
[87] Ex. H (ASA Guidelines) at 247.
[88] *Id.*
[89] Ex. A (Affidavit) at ¶ 29.

100. Rather than state that PRoFESS showed no difference between the two drugs, BMS/Sanofi compelled its sales force to emphasize that "Aggrenox failed to meet the primary end point of noninferiority for recurrent stroke relative to Plavix."[90] BMS/Sanofi further claimed that "it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients."[91] Despite the inconclusiveness of the PRoFESS data, the ASA still recommends Aggrenox over Plavix due to substantially more clinical data favoring its use in stroke patients.[92] The purpose of talking to physicians about the PRoFESS trial was to increase Plavix's market share in the post-stroke population.[93]

**D. BMS/Sanofi targeted doctors whose patients rely on Government Payors for health care treatment so as to wrongfully inflate sales and profits at a tremendous cost to American taxpayers.**

101. BMS/Sanofi focused sales calls on physicians who prescribed medication for large populations of patients covered by Government Payors.[94] The purpose of targeting such patients was based on physicians' inherent willingness to prescribe more expensive drugs to patients who relied on government assistance in obtaining prescription medication.[95] Accordingly, Plavix provided a unique two-fold opportunity for BMS/Sanofi to capitalize on Government Payors by illegally raiding government coffers.[96]

102. First, during the relevant period, Plavix enjoyed—and will enjoy through most of 2011—continued patent protection, meaning no generic prescription equivalent is available.[97]

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[90] *Id.*; Ex. E (PRoFESS Summary) at 2.

[91] Ex. A (Affidavit) at ¶ 29; Ex. E (PRoFESS Summary) at 5.
[92] *See* Ex. H (ASA Guidelines); Ex. A (Affidavit) at ¶ 30.
[93] Ex. A (Affidavit) at ¶ 31.
[94] *Id.* at ¶¶ 32-38.
[95] *Id.* at ¶ 33.
[96] *Id.* at ¶ 34.
[97] *See* United States Food & Drug Admin. Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, *available at*

Therefore, if a doctor wishes to prescribe clopidogrel, Plavix is her only option.[98] Second, by making fraudulent claims regarding Plavix's efficacy against aspirin, BMS/Sanofi convinced many physicians of Plavix's false superiority to aspirin and its unique qualities.[99] This scheme left many physicians with the false impression that Plavix was essentially the only option for effective patient care in a host of contexts.[100]

103. Together, BMS/Sanofi's concerted efforts created a perfect storm to generate astronomical sales and profits fraudulently created by bilking federal and state governments.[101]

## VI.
## CAUSES OF ACTION

### A. First Cause of Action: Federal False Claims Act Violations (31 U.S.C. § 3729-3733)

104. Dickson realleges and incorporates by reference each of the preceding paragraphs as if set forth fully herein.

105. This Count is brought by Plaintiff-Relator in the name of the United States against the Defendants under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violation of 31 U.S.C. § 3729(a)(1) and (a)(2). In violation of 31 U.S.C. § 3729(a)(1) and (a)(2), Defendants made and caused to be made, the false claims that have been set forth in the Complaint herein.

106. Plaintiff United States, unaware of the falsity of the claims and/or statements which Defendants caused doctors, pharmacists, and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid those doctors, pharmacies and other health care providers for claims that would otherwise not have been allowed.

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http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm (last visited March 17, 2011) (indicating that Plavix remains on patent until November 17, 2011); *see also* Ex. A (Affidavit) at ¶ 35.

[98] Ex. A (Affidavit) at ¶ 35.

[99] *Id.* at ¶ 36.

[100] *Id.* at ¶ 37.

[101] *Id.* at ¶ 38.

107. The amounts of the false or fraudulent claims to the United States were material.

108. Plaintiff United States, being unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy thereof, paid and may continue to pay Defendants for health care services that otherwise should not have been paid under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, and the Federal Health Benefit Program, and other federal health care programs.

109. The United States and the state Medicaid programs have been damaged by the payment of false or fraudulent claims.

110. By virtue of the above-described acts, among others, BMS/Sanofi did knowingly and willfully promote Plavix for off-label and dangerous uses from at least 1996 onwards.

111. BMS/Sanofi knowingly presented physicians with false information regarding the efficacy of Plavix compared to cheaper alternatives such as aspirin. BMS/Sanofi manipulated, misrepresented, and/or withheld clinical data from physicians in order to convince physicians to prescribe Plavix.

112. BMS/Sanofi's actions caused physicians to submit numerous prescriptions for Plavix for reimbursement by Government Payors. BMS/Sanofi's actions knowingly caused physicians and pharmacists to either expressly or impliedly make false certifications about Plavix's efficacy or necessity for the patient's treatment. As a result, BMS/Sanofi knowingly caused the submission of false claims for payment by Government Payors. BMS/Sanofi's actions were in violation of the False Claims Act, 31 U.S.C. ¶¶ 3729-3733.

113. The United States made payment on these false or fraudulent claims. Had the United States known that BMS/Sanofi were knowingly causing physicians and pharmacists to

submit such false claims for payment, the United States would not have provided reimbursement for such prescriptions under Government Payors programs.

114. As a result, the United States has suffered and continues to suffer substantial damage.

**B. Second Cause of Action: Federal False Claims Act Violations for Conspiracy (31 U.S.C. § 3729(a))**

115. Dickson realleges and incorporates by reference each of the preceding paragraphs as if set forth fully herein.

116. Defendants BMS/Sanofi have conspired to defraud the Government by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval.

117. Defendants BMS/Sanofi have conspired to defraud the Government by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.

118. Defendants BMS/Sanofi have conspired to defraud the Government by knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government.

119. As a result, the United States has suffered and continues to suffer substantial damage.

**C. Third Cause of Action: Illinois State Law Claims for Violations of the Illinois Whistleblower Reward and Protection Act (740 ILCS 175, *et seq.*)**

120. Dickson realleges and incorporates by reference each of the preceding paragraphs as if set forth fully herein.

121. Pursuant to Section 3 of the Illinois Whistleblower Reward and Protection Act, a person is liable to the state of Illinois for civil penalties and triple damages for any damage the state sustains as a result of fraud perpetrated by that person on the state, such as for knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval, or making or using false records or statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the state.[102]

122. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Illinois governments while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Illinois and specifically within the Southern District of Illinois.

123. Over 40% of nationwide Plavix sales are covered by Government Payors. Illinois is the fifth most populous state in the United States. A significant percentage of Illinois Plavix sales are covered by Government Payors in Illinois.

124. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

125. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Illinois in extreme jeopardy. Had the State of Illinois known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to

[102] 740 ILCS 175/3(a)(7).

the State of Illinois – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

126. Additionally, had the State of Illinois known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Illinois. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

127. If the State of Illinois had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

128. Dickson brings this action for violations of the Illinois Whistleblower Reward and Protection Act.[103]

**D. Fourth Cause of Action: Illinois State Law Claims for Violations of the Illinois Medical Assistance Fraud (305 ILCS 5/8A-1 *et seq.*)**

129. Dickson realleges and incorporates by reference each of the preceding paragraphs as if set forth fully herein.

130. Pursuant to Section 8A-7 of the Illinois Public Assistance Fraud Act, a person is liable to the state of Illinois for civil penalties and triple damages for any damage the state sustains as a result of fraud perpetrated by that person on the state, if the person willfully, by

[103] 740 ILCS 175/4(b)(1).

means of a false statement or representation, or by concealment of any material fact or by other fraudulent scheme or device on behalf of himself or others, obtains or attempts to obtain benefits or payments under this Code to which he or it is not entitled, or in a greater amount than that to which he or it is entitled.[104]

131. Upon information and belief, BMS/Sanofi willfully or knowingly participated in a comprehensive scheme to defraud the Illinois governments while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Illinois and specifically within the Southern District of Illinois.

132. Over 40% of nationwide Plavix sales are covered by Government Payors. Illinois is the fifth most populous state in the United States. A significant percentage of Illinois Plavix sales are covered by Government Payors in Illinois.

133. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

134. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Illinois in extreme jeopardy. Had the State of Illinois known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Illinois – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this

combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

135. Additionally, had the State of Illinois known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Illinois. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

136. Dickson brings this action on behalf of the United States and the State of Illinois for violations of the Illinois Public Assistance Fraud Act.

## E. Fifth Cause of Action: California State Law Claims for Violations of the California False Claims Act (Cal. Government Code §§ 12650-12655)

137. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

138. This is a claim against BMS/Sanofi for treble damages and penalties on behalf of the State of California under the California False Claims Act, California Government Code §§ 12650-12655.

139. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

140. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of California in

[104] 305 ILCS 5/8A-7.

extreme jeopardy. Had the State of California known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of California – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

141. Additionally, had the State of California known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of California. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

142. If the State of California had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

143. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the California government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of California.

144. By virtue of the above-described unlawful acts, BMS/Sanofi knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to

induce the California State Government to approve and pay such false and fraudulent claims under the Medicaid program.

145. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

146. By reason of Defendants' conspiracy and unlawful acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

147. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**F. Sixth Cause of Action: Delaware State Law Claims for Violations of the Delaware False Claims and Reporting Act (6 Del C. §1201(a)(1) and (2))**

148. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

149. This is a claim for treble damages and penalties against BMS/Sanofi on behalf of the State of Delaware under the Delaware False Claims and Reporting Act, 6 Del C. §1201(a)(1) and (2).

150. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

151. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Delaware in extreme jeopardy. Had the State of Delaware known of the extreme danger presented by the

concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Delaware – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

152. Additionally, had the State of Delaware known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Delaware. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

153. If the State of Delaware had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

154. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Delaware government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Delaware.

155. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

156. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

157. By reason of Defendants' conspiracy and unlawful acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

158. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**G. Seventh Cause of Action: District of Columbia Claims for Violations of the District of Columbia Procurement Reform Amendment Act (D.C. CODE ANN. §§ 2-308.13-.15)**

159. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

160. This is a claim for treble damages and penalties against BMS/Sanofi on behalf of the District of Columbia under the District of Columbia Procurement Reform Amendment Act.

161. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

162. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the District of Columbia in extreme jeopardy. Had the District of Columbia known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the

concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the District of Columbia – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

163. Additionally, had the District of Columbia known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the District of Columbia. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

164. If the Distirct of Columbia had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

165. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the District of Columbia government while illegally and deceptively promoting Plavix to further increase Plavix sales within the District of Columbia.

166. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

167. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

168. By reason of the Defendants' unlawful acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

169. The District of Columbia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

## H. Eighth Cause of Action: Florida State Law Claims for Violations of the Florida False Claims Act (Fl. Stat. §68.081-68.090)

170. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

171. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Florida under the Florida False Claims Act, Fl.Stat. §68.081-68.090.

172. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

173. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Florida in extreme jeopardy. Had the State of Florida known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Florida – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this

combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

174. Additionally, had the State of Florida known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Florida. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

175. If the State of Florida had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

176. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Florida government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Florida.

177. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

178. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

179. By reason of the Defendants' unlawful acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

180. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

## I. Ninth Cause of Action: Hawaii State Law Claims for Violations of the Hawaii False Claims Act (HAW. REV. STAT. §§661-21 to 661-29)

181. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

182. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Hawaii under the HAW. REV. STAT. §661-21(a)(3).

183. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

184. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Hawaii in extreme jeopardy. Had the State of Hawaii known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Hawaii – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

185. Additionally, had the State of Hawaii known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Hawaii. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

186. If the State of Hawaii had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

187. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Hawaii government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Hawaii.

188. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

189. By reason of the Defendants' unlawful acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

190. The State of Hawaii's Medicaid Program has been damaged by the payment of false and fraudulent claims.

**J. Tenth Cause of Action: Nevada State Law Claims for Violations of the Nevada False Claims Act (NEV. REV. STAT. ANN. §357.01-.250)**

191. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

192. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Nevada under the Nevada False Claims Act.

193. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

194. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Nevada in extreme jeopardy. Had the State of Nevada known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Nevada – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

195. Additionally, had the State of Nevada known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of

Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Nevada. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

196. If the State of Nevada had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

197. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Nevada government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Nevada.

198. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

199. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

200. By reason of the Defendants' unlawful acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

201. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

## K. Eleventh Cause of Action: Tennessee State Law Claims for Violations of the Tennessee Medicaid False Claims Act (Tenn. Code. Ann. §71-5-181 to -185)

202. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

203. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Tennessee under the Tennessee Medicaid False Claims Act.

204. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

205. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Tennessee in extreme jeopardy. Had the State of Tennessee known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Tennessee – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

206. Additionally, had the State of Tennessee known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Tennessee. Furthermore, had pharmacists known of the extreme danger

posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

207. If the State of Tennessee had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

208. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Tennessee government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Tennessee.

209. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

210. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

211. By reason of the Defendants' unlawful acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

212. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

## L. Twelfth Cause of Action: Texas State Law Claims for Violations of the Texas Medicaid Fraud Prevention Act (TEX. HUM. RES. CODE ANN 36.001-.132)

213. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

214. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Texas under the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN.36.001–.132.

215. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

216. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Texas in extreme jeopardy. Had the State of Texas known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Texas – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

217. Additionally, had the State of Texas known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Texas. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

218. If the State of Texas had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

219. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Texas government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Texas.

220. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

221. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

222. By reason of the Defendants' unlawful acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

223. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

## M. Thirteenth Cause of Action: Virginia State Law Claims for Violations of the Virginia Fraud Against Taxpayers Act (VA CODE ANN. 8.01-2.16. 1-216.19)

224. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

225. This is a claim for treble damages and penalties against the Defendants on behalf of the Commonwealth of Virginia under the Virginia Fraud Against Taxpayers Act, Vested. Ch. 842, Article 19.1, § 8.01-216.1 et seq.

226. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

227. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the commonwealth of Virginia in extreme jeopardy. Had the Commonwealth of Virginia known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the Commonwealth of Virginia – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

228. Additionally, had the Commonwealth of Virginia known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the Commonwealth of Virginia. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

229. If the Commonwealth of Virginia had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

230. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Virginia government while illegally and deceptively promoting Plavix to further increase Plavix sales within the Commonwealth of Virginia.

231. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

232. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

233. By reason of the Defendants' unlawful acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

234. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

## N. Fourteenth Cause of Action: Georgia State Law Claims for Violations of the Georgia False Medicaid Claims Act (Ga. Code 49-4-168 *et seq.*)

235. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

236. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Georgia under the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 et seq.

237. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

238. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Georgia in extreme jeopardy. Had the State of Georgia known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Georgia – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

239. Additionally, had the State of Georgia known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Georgia. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

240. If the State of Georgia had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

241. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Georgia government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Georgia.

242. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

243. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

244. By reason of the Defendants' unlawful acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

245. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

## O. Fifteenth Cause of Action: Indiana State Law Claims for Violations of the Indiana State False Claims and Whistleblowers Protection Act (IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18)

246. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

247. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Indiana under the Indiana State False Claims and Whistleblowers Protection Act, IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18.

248. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

249. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Indiana in extreme jeopardy. Had the State of Indiana known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Indiana – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

250. Additionally, had the State of Indiana known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Indiana. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

251. If the State of Indiana had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

252. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Indiana government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Indiana.

253. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

254. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

255. By reason of the Defendants' unlawful acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

**P. Sixteenth Cause of Action: Michigan State Law Claims for Violations of the Michigan Medicaid False Claims Act (MICH. COMP LAWS § 400.601-400.613)**

256. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

257. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

258. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Michigan in

extreme jeopardy. Had the State of Michigan known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Michigan – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

259. Additionally, had the State of Michigan known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Michigan. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

260. If the State of Michigan had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

261. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Michigan government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Michigan.

262. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

263. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

264. By reason of the Defendants' unlawful acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

265. The Michigan State Medicaid Program has been damaged by the payment of false and fraudulent claims.

**Q. Seventeenth Cause of Action: Montana State Law Claims for Violations of the Montana False Claims Act (MONT. CODE ANN. § 17-8-401 – 17-8-412)**

266. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

267. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

268. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Montana in extreme jeopardy. Had the State of Montana known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to

the State of Montana – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

269. Additionally, had the State of Montana known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Montana. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

270. If the State of Montana had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

271. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Montana government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Montana.

272. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

273. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid

and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

274. By reason of the Defendants' unlawful acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

275. The Montana State Medicaid Program has been damaged by the payment of false and fraudulent claims.

**R. Eighteenth Cause of Action: New Hampshire State Law Claims for Violations of the New Hampshire False Claims Act (N.H. REV. STAT. ANN. § 167:58-167:61-b)**

276. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

277. This is a claim for treble damages and penalties against Defendants on behalf of the State of New Hampshire under the New Hampshire False Claims Act, N.H. REV. STAT. ANN. §167:61-b.

278. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

279. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of New Hampshire in extreme jeopardy. Had the State of New Hampshire known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of New Hampshire – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this

combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

280. Additionally, had the State of New Hampshire known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of New Hampshire. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

281. If the State of New Hampshire had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

282. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New Hampshire government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of New Hampshire.

283. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

284. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

285. By reason of the Defendants' unlawful acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

286. The State of New Hampshire is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**S. Nineteenth Cause of Action: New Mexico State Law Claims for Violations of the New Mexico Medicaid False Claims Act (N.M. STAT. ANN. § 27-14-1- - 27-14-15)**

287. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

288. This is a claim for treble damages and penalties against all Defendants on behalf of the State of New Mexico under the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1- 27-14-15.

289. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

290. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of New Mexico in extreme jeopardy. Had the State of New Mexico known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of New Mexico – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this

combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

291. Additionally, had the State of New Mexico known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of New Mexico. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

292. If the State of New Mexico had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

293. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New Mexico government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of New Mexico.

294. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

295. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

296. By reason of the Defendants' unlawful acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

**T. Twentieth Cause of Action: New York State Law Claims for Violations of the New York False Claims Act (N.Y. St. Finance Law §187 *et seq*.)**

297. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

298. This is a claim for treble damages and penalties against all Defendants on behalf of the State of New York under the New York False Claims Act, N.Y. St. Finance Law §187 et seq.

299. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

300. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of New York in extreme jeopardy. Had the State of New York known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of New York – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

301. Additionally, had the State of New York known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have

approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of New York. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

302. If the State of New York had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

303. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New York government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of New York.

304. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

305. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

306. By reason of the Defendants' unlawful acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

307. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**U. Twenty-First Cause of Action: Massachusetts State Law Claims for Violations of the Massachusetts False Claims Act (Massachusetts Gen. Laws c.12 §5(A))**

308. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

309. This is a claim for treble damages and penalties against the Defendants on behalf of the Commonwealth of Massachusetts under the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A).

310. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

311. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the Commonwealth of Massachusetts in extreme jeopardy. Had the Commonwealth of Massachusetts known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the Commonwealth of Massachusetts – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

312. Additionally, had the Commonwealth of Massachusetts known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate

false claim was submitted to the Commonwealth of Massachusetts. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

313. If the Commonwealth of Massachusetts had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

314. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Massachusetts government while illegally and deceptively promoting Plavix to further increase Plavix sales within the Commonwealth of Massachusetts.

315. By virtue of the above-described acts, Defendants knowingly made, used, or caused the Commonwealth of Massachusetts to approve and pay such false and fraudulent claims.

316. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

317. By reason of the Defendants' unlawful acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

## V. Twenty-Second Cause of Action: Illinois State Law Claims for Violations of the City of Chicago False Claims Act (Municipal Code of Chicago §1-22-010-§1-22-060)

318. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

319. This is a claim for treble damages and penalties against all Defendants on behalf of the City of Chicago under the Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060.

320. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

321. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the City of Chicago in extreme jeopardy. Had the City of Chicago known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the City of Chicago – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

322. Additionally, had the City of Chicago known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the City of Chicago. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

323. If the City of Chicago had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

324. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Chicago government while illegally and deceptively promoting Plavix to further increase Plavix sales within the City of Chicago.

325. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Chicago City Government to approve and pay such false and fraudulent claims.

326. The Chicago City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

327. By reason of the Defendants' unlawful acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

## W. Twenty-Third Cause of Action: New Jersey State Law Claims for Violations of the New Jersey False Claims Act (N.J. STAT. §2A:32C-1-17)

328. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

329. This is a claim for treble damages and penalties against the Defendants on behalf of the State of New Jersey under the New Jersey False Claims Act N.J. STAT. §2A:32C-1-17.

330. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

331. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of New Jersey in extreme jeopardy. Had the State of New Jersey known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of New Jersey – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

332. Additionally, had the State of New Jersey known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of New Jersey. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

333. If the State of New Jersey had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

334. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New Jersey government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of New Jersey.

335. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of New Jersey to approve and pay such false and fraudulent claims.

336. The State of New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

337. By reason of the Defendants' unlawful acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

## X. Twenty-Fourth Cause of Action: Rhode Island State Law Claims for Violations of Rhode Island's State False Claims Act (R.I. Gen. Laws § 9-1.1-1 – 9-1.1-8)

338. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

339. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Rhode Island's False Claims Act R.I. Gen. Laws § 9-1.1-3.

340. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

341. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Rhode Island in extreme jeopardy. Had the State of Rhode Island known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for

such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Rhode Island – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

342. Additionally, had the State of Rhode Island known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Rhode Island. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

343. If the State of Rhode Island had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

344. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Rhode Island government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Rhode Island.

345. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Rhode Island to approve and pay such false and fraudulent claims.

**Y. Twenty-Fifth Cause of Action: Wisconsin State Law Claims for Violations of the Wisconsin False Claims Act (Wis. Stat. § 20.931)**

346. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

347. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Wisconsin's False Claims Act Wis. Stat. § 20.931.

348. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

349. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Wisconsin in extreme jeopardy. Had the State of Wisconsin known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Wisconsin – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

350. Additionally, had the State of Wisconsin known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Wisconsin. Furthermore, had pharmacists known of the extreme danger

posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

351. If the State of Wisconsin had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

352. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Wisconsin government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Wisconsin.

353. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Wisconsin to approve and pay such false and fraudulent claims.

## Z. Twenty-Sixth Cause of Action: Oklahoma State Law Claims for Violations of the Oklahoma False Claims Act (63 Okl. St. §5053-5053.7)

354. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

355. Plaintiff-Relator incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

356. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

357. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Oklahoma in extreme jeopardy. Had the State of Oklahoma known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the

concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Oklahoma – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

358. Additionally, had the State of Oklahoma known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Oklahoma. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

359. If the State of Oklahoma had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

360. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Oklahoma government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Oklahoma.

361. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Oklahoma to approve and pay such false and fraudulent claims.

## AA. Twenty-Seventh Cause of Action: North Carolina State Law Claims for Violations of the North Carolina False Claims Act (N.C. Gen. Stat. § 1-605 – 618, §108A-63)

362. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

363. This is a claim for treble damages and penalties against the Defendants on behalf of the State of North Carolina under the North Carolina False Claims Act N.C. Gen. Stat. § 1-605-618, §108A-63.

364. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

365. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of North Carolina in extreme jeopardy. Had the State of North Carolina known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of North Carolina – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

366. Additionally, had the State of North Carolina known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of North Carolina. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

367. If the State of North Carolina had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

368. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the North Carolina government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of North Carolina.

369. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of North Carolina to approve and pay such false and fraudulent claims.

370. By reason of the Defendants' unlawful acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

**BB. Twenty-Eighth Cause of Action: Minnesota State Law Claims for Violations of the Minnesota False Claims Act (Minn. Stat. § 15.C01 *et. seq*)**

371. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

372. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Minnesota under the Minnesota False Claims Minn. Stat. § 15.C01 et. seq.

373. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

374. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Minnesota in extreme jeopardy. Had the State of Minnesota known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the

concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Minnesota – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

375. Additionally, had the State of Minnesota known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Minnesota. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

376. If the State of Minnesota had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

377. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Minnesota government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Minnesota.

378. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Minnesota to approve and pay such false and fraudulent claims.

379. By reason of the Defendants' unlawful acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

**CC. Twenty-Ninth Cause of Action: Maryland State Law Claims for Violations of the Maryland False Health Claims Act of 2010 (Subtitle 6, False Claims Against State Health Plans and State Health Programs, §2-601 *et seq.*)**

380. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

381. This is a claim for treble damages and penalties under the Maryland False Health Claims Act of 2010, Subtitle 6.

382. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

383. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

384. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal business practices.

385. By reason of the Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

386. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

387. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Maryland in

extreme jeopardy. Had the State of Maryland known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Maryland – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

388. Additionally, had the State of Maryland known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Maryland. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

389. If the State of Maryland had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

390. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Maryland government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Maryland.

391. The State of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

**DD. Thirtieth Cause of Action: Colorado State Law Claims for Violations of the Colorado Medicaid False Claims Act (C.R.S. § 25.5-4-304 *et seq.*)**

392. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

393. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act C.R.S. § 25.5-4-304 et seq.

394. The Colorado Medicaid False Claims Act C.R.S. § 25.5-4-304 et seq. provides for liability for inter alia any person who engages in any or all of the following conduct.

> (a) Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> (c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;
>
> (d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> …
>
> (f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act", or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act";
>
> (g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).

395. By virtue of the conduct alleged herein, including the exchange of kickbacks and submissions of non-reimbursable claims described above, Defendants knowingly violated each of the above subsections of the Colorado Medicaid False Claims Act by and through their intentional and/or knowing violations of federal and state laws, including the Anti-Kickback Statute, as described herein.

396. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of Defendants' illegal conduct, paid for claims that otherwise would not have been allowed.

397. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

398. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Colorado in extreme jeopardy. Had the State of Colorado known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Colorado – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

399. Additionally, had the State of Colorado known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the

use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Colorado. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

400. If the State of Colorado had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

401. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Colorado government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Colorado.

402. By reason of these improper payments, the Colorado Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

**EE. Thirty-First Cause of Action: Connecticut State Law Claims for Violations of the Connecticut Medicaid False Claims Act (CHAPTER 319v Sec. 17b-301a *et seq*.)**

403. Dickson incorporates by reference and re-alleges all above paragraphs as if fully set forth herein.

404. This is a claim for treble damages and penalties under the Connecticut Medicaid False Claims Act CHAPTER 319v Sec. 17b-301a et seq.

405. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, to an officer or employee of the State of Connecticut, false or fraudulent claims for payment or approval under medical assistance programs administered by the Department of Social Services.

406. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to secure the

payment or approval by the State of Connecticut false or fraudulent claims under medical assistance programs administered by the Department of Social Services.

407. By virtue of the acts described above, Defendants conspired with each other and with others to defraud the State of Connecticut by securing the allowance or payment of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services.

408. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

409. By reason of the Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

410. By virtue of the above-described acts, among others, Defendants BMS/Sanofi did knowingly and willfully promote Plavix for dangerous uses from at least 1996 onwards.

411. BMS/Sanofi's willful and reckless concealment of the dangerous consequences of using Plavix concomitantly with CYP2C19 inhibitors and/or for patients who are poor CYP2C19 metabolizers has placed and continues to place residents and citizens of the state of Connecticut in extreme jeopardy. Had the State of Connecticut known of the extreme danger presented by the concomitant use of Plavix and CYP2C19 inhibitors, it would not have approved payment for such concomitant usage. Accordingly, each time a physician wrote prescriptions for the concomitant use of Plavix and CYP2C19 inhibitors, two separate false claims were submitted to the State of Connecticut – one for the Plavix prescription and one for the CYP2C19 inhibitor prescription. Furthermore, had pharmacists known of the extreme danger posed by this

combination, they would have refused to fill concomitant prescriptions of Plavix and the CYP2C19 inhibitor.

412. Additionally, had the State of Connecticut known of the extreme danger presented by the use of Plavix by patients who are poor CYP2C19 metabolizers, it would not have approved payment for the Plavix. Accordingly, each time a physician wrote prescriptions for the use of Plavix by patients who are poor CYP2C19 metabolizers, a separate false claim was submitted to the State of Connecticut. Furthermore, had pharmacists known of the extreme danger posed by the use of Plavix by patients who are poor CYP2C19 metabolizers, they would have refused to authorize payment for the Plavix prescription.

413. If the State of Connecticut had known of the false statements disseminated by BMS/Sanofi in support of Plavix, they would have refused to authorize payment for the the Plavix prescription.

414. Upon information and belief, BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the Connecticut government while illegally and deceptively promoting Plavix to further increase Plavix sales within the state of Connecticut.

415. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

## VII.
## DEMAND FOR JURY TRIAL

416. Pursuant to Federal Rule of Civil Procedure 38, Dickson demands a trial by jury.

## VIII.
## PRAYER

WHEREFORE, Relator Elisa Dickson respectfully requests that this Court enter judgment on behalf of the United States against Defendants for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the United States as a result of Defendants' conduct;

b. Civil penalties against Defendants up to $10,000, plus the appropriate amount of inflation, for each violation of 31 U.S.C. § 3729;

c. Dickson be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

d. Dickson be awarded all costs and expenses of this litigation, including attorneys' fees and costs of court; and

e. All other relief on behalf of the United States Government to which it may be entitled and that the Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Illinois against Defendants for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the State of Illinois as a result of Defendants' conduct pursuant to 740 ILCS 175;

b. Civil penalties against Defendants up to $11,000 for each violation of 740 ILCS 175;

c. Dickson be awarded the maximum amount allowed pursuant to 740 ILCS 175/4(d);

d. Repayment of any excess benefits or payments received pursuant to 305 ILCS 5/8A-7;

e. Civil penalties against Defendants consisting of the interest on the amount of excess benefits or payments pursuant to 305 ILCS 5/8A-7;

f. Damages in the amount of three (3) times the amount of such excess benefits or payments pursuant to 305 ILCS 5/8A-7;

g. Damages in the amount of $2,000 for each excessive claim for benefits or payments pursuant to 305 ILCS 5/8A-7;

h. Dickson be awarded all costs and expenses of this litigation, including attorneys' fees and costs of court; and

i. All other relief on behalf of the State of Illinois to which it may be entitled and that the Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of California against Defendants for the following:

a. That by reason of the aforementioned violations of the California False Claims Act that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that California has sustained because of XXXX's actions, plus a civil penalty of not more than $10,000 for each violation of CAL. GOV. CODE §12651(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to CAL. GOV. CODE §12652(g)(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Delaware against Defendants for the following:

a. That by reason of the aforementioned violations of the Delaware false claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Delaware has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of DEL. CODE ANN. TIT. 6 §1201(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to DEL. CODE ANN. §1205(a) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the District of Columbia against Defendants for the following:

a. That by reason of the aforementioned violations of the District of Columbia false claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of DC. CODE ANN. §2-308.14(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant DC. CODE ANN. §2-308.15(f)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Florida against Defendants for the following:

a. That by reason of the aforementioned violations of the Florida false claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Florida has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of FLA. STAT. ANN. §68.082(2)(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant FLA. STAT. ANN. §68.085(1)-(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Hawaii against Defendants for the following:

a. That by reason of the aforementioned violations of the Hawaii's false claim provisions that this Court enter judgment in Plaintiff's favor and against

Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Hawaii has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of HAW. REV. STAT. §661-21(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant HAW. REV. STAT. §661-27(a) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Nevada against Defendants for the following:

a. That by reason of the aforementioned violations of the Nevada false claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Nevada has sustained because of Defendants' actions, plus a civil penalty of not more than $10,000 for each violation of the NEV. REV. STAT. ANN. §357.014(1)(c);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Nev. Rev. Stat. Ann. §357,210(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Tennessee against Defendants for the following:

a. That by reason of the aforementioned violations of the Tennessee false claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Tennessee has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of the TENN. CODE ANN. §71-5-182(a)(1)(C);

b. That Relator, as Qui *Tam* Plaintiff, be awarded the maximum amount allowed pursuant Tenn. Code. Ann. §71-5-183(c)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Texas against Defendants for the following:

a. That by reason of the aforementioned violations of the Texas Medicaid Fraud Prevention Statute that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to two times the amount of damages that the state of Texas has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $15,000 fore each violation of TEX. HUM. RES. CODE ANN. § 36.002(8) that results in injury to an elderly person, a disabled person, or a person younger than 18 years of age, or not less than $1,000 and not more than $10,000 for each violation of the TEX. HUM. RES. CODE ANN. § 36.002(8) that does not result in an injury to a person;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant TEX. HUM. RES. CODE ANN. § 36.110 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the Commonwealth of Virginia against Defendants for the following:

a. That by reason of the aforementioned violations of the Virginia Fraud Against Taxpayers Act that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of the VA. CODE ANN. § 8.01-216.3(A)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant VA. CODE ANN. § 8.01-216.7 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Georgia against Defendants for the following:

a. That by reason of the aforementioned violations of the Georgia False Medicaid Claims Act that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Georgia has sustained because of Defendants' actions, plus a civil penalty of not more than $10,000 for each violation of the GA. CODE ANN. § 49-4-168.1;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the GA. CODE ANN. § 49-4-168.2 (I) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Indiana against Defendants for the following:

a. That by reason of the aforementioned violations of the Indiana State False Claims and Whistleblowers Protection Act that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Indiana has sustained because of Defendants' actions, plus a civil penalty of less than $5,000 for each violation of the IND. CODE ANN. § 5-11-5.5-2;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the IND. CODE ANN. § 5-11-5.5-6 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Michigan against Defendants for the following:

a. That by reason of the aforementioned violations of the Michigan State Medicaid False Claims Act that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to three times the amount of damages that the Michigan has sustained because of Defendants' actions, plus a civil penalty of equal to the full amount XXXX unjustly received as a result of its unlawful conduct for violating MICH. COMP LAWS § 400.603, 606 and 607;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the MICH. COMP LAWS § 400.610 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Montana against Defendants for the following:

a. That by reason of the aforementioned violations of the Montana False Claims Act that this Court enter judgment in Plaintiff's favor and against XXXX in an amount equal to not less than two times and not more than three times the amount of damages that the Montana has sustained because of XXXX's actions, plus a civil penalty of not more than $10,000 for each violation of the MONT. CODE ANN. § 17-8-403;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the MONT. CODE ANN. § 17-8-410 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of New Hampshire against Defendants for the following:

a. That by reason of the aforementioned violations of the New Hampshire false claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that New Hampshire has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of the N.H. REV. STAT. ANN. §167:61-b;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.H. REV. STAT. ANN. §167:61-b and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of New Mexico against Defendants for the following:

a. That by reason of the aforementioned violations of the New Mexico False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount three times the amount of damages that New Mexico has sustained because of Defendants' actions for violation of the N.M. STAT. ANN. § 27-14-4;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.M. STAT. ANN. § 27-14-9 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of New York against Defendants for the following:

a. That by reason of the aforementioned violations of the New York False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three

times the amount of damages that New York has sustained because of Defendants' actions, plus a civil penalty of not less than $6,000 and not more than $12,000 for each violation of N.Y. STATE FIN. LAW § 189;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.Y. STATE FIN. LAW § 119(6) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Massachusetts against Defendants for the following:

a. That by reason of the aforementioned violations of the Massachusetts False Claims Act provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount three times the amount of damages that Massachusetts has sustained because of Defendants' actions for violation of the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of New Jersey against Defendants for the following:

a. That by reason of the aforementioned violations of the New Jersey False Claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of New Jersey has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of N.J. STAT. §2A:32C-1-17;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.J. STAT. §2A:32C-1-17 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Rhode Island against Defendants for the following:

a. That by reason of the aforementioned violations of Rhode Island's False Claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of R.I. Gen. Laws § 9-1/1-3;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant R.I. Gen. Laws § 9-1.1-4(d) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Wisconsin against Defendants for the following:

a. That by reason of the aforementioned violations of Wisconsin's False Claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of Wis. Stat. § 20.931;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Wis. Stat. § 20.931 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Oklahoma against Defendants for the following:

a. That by reason of the aforementioned violations of Oklahoma's False Claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of 63 Okl. St. §5053.1.4;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant 63 Okl. St. §5053.1.4 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs *incurred* in the prosecution of this suit; and

d. That *Plaintiff* and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of North Carolina against Defendants for the following:

a. That by reason of the aforementioned violations of the North Carolina False Claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of North Carolina has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of N.C. Gen. Stat. § 1-605-618, §108A-63;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the N.C. Gen. Stat. § 1-605-618, §108A-63 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the State of Minnesota against Defendants for the following:

a. That by reason of the aforementioned violations of the Minnesota False Claims provisions that this Court enter judgment in Plaintiff's favor and against Defendants in an amount equal to not less than two times and not more than three

times the amount of damages that the state of North Carolina has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of Minn. Stat. § 15.C01 *et. seq*;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Minn. Stat. § 15.C01 *et. seq* and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Relator Elisa Dickson further respectfully requests that this Court enter judgment on behalf of the City of Chicago and the States of Maryland, Colorado and Connecticut against Defendants for the any such relief to which Relator may be justly entitled.

Relator Elisa Dickson further respectfully requests any such other and further relief to which she may be justly entitled.

Respectfully submitted,

BY: /s./Christopher Cueto

Christopher Cueto, #06192248
LAW OFFICE OF CHRISTOPHER CUETO, LTD.
7110 West Main Street
Belleville, IL 62223
Phone: (618) 277-1554
Fax: (618) 277-0962

**LEAD COUNSEL FOR RELATOR/ PLAINTIFF**

Robert L. Salim, Bar #11663
ATTORNEY AT LAW
1901 Texas Street
Natchitoches, LA 71457
Phone: (318) 352-5999
Fax: (318) 352-5998

Ralph D. McBride
Douglas A. Daniels
Tony L. Visage
Heath A. Novosad
BRACEWELL & GIULIANI LLP
711 Louisiana Street, Suite 2300
Houston, Texas 77002-2781
Phone: (713) 223-2300
Fax: (713) 221-1212

Kenneth T. Fibich
FIBICH HAMPTON LEEBRON
BRIGGS & JOSEPHSON, LLP
1150 Bissonnet
Houston, TX 77005
Phone: (713) 751-0025
Fax: (713) 751-0030

Jeffrey D. Meyer
MOULTON & MEYER LLP
800 Taft
Houston, Texas 77019
Phone: (713) 353-6699
Fax: (713) 353-6698

**ATTORNEYS FOR RELATOR/PLAINTIFF**

## CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2011, I electronically filed the foregoing **FIRST AMENDED ORIGINAL COMPLAINT** with the Clerk of U.S. District Court using the CM/ECF system.

Respectfully submitted,

/s./ Christopher Cueto
Christopher Cueto, IL #06192248
Law Office of Christopher Cueto, Ltd.
7110 West Main Street
Belleville, IL 62223
Phone: (618) 277-1554
Fax: (618) 277-0962